



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,011	12/05/2001	Eric Douglas Bastian	006038.00002	3038

22907 7590 10/01/2003

BANNER & WITCOFF
1001 G STREET N W
SUITE 1100
WASHINGTON, DC 20001

EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
----------	--------------

1651

DATE MAILED: 10/01/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/002,011

Applicant(s)

BASTIAN ET AL.

Examiner

Ruth A. Davis

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 8-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1651

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1 – 7 in Paper No. 6 is acknowledged. Claims 8 – 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 – 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method for treating a disorder selected from high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, hypertensive disorders of pregnancy, type 2 diabetes, depression, asthma, inflammatory bowel disease, attention deficit disorder, migraine headaches, kidney disease, hypercholesterolaemia, congestive heart failure, or immune deficiency, wherein an effective amount of milk mineral is administered. The claimed invention

Art Unit: 1651

does not enable any person skilled in the art to make and use the method without undue experimentation because the specification fails to set forth direction or guidance to teach one in the art how to treat or prevent (as defined by applicant) any of the named disorders. The specification lacks examples of treatment and does not disclose dosages, amounts, ranges, methods or modes of administration, thereby failing to indicate any evidence of success. Furthermore, there is no commonality among the named disorders such that one would expect the method to be successful in each disorder based on another. Moreover, since the specification fails to set forth even a single method of treatment, and there is neither a starting point nor hint of how to practice the claimed method; the claims are not enabled by the specification.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is drawn to a method of treating, however is rendered vague and indefinite because it is unclear if the recited amounts of calcium, phosphorous, inorganic or organic minerals are part of the total mineral amount, or if they are in addition to the previously named amounts of minerals.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1 – 3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Govers et al. (1994).

Applicant claims a method for treating a disorder selected from high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, hypertensive disorders of pregnancy, type 2 diabetes, depression, asthma, inflammatory bowel disease, attention deficit disorder, migraine headaches, kidney disease, hypercholesterolaemia, congestive heart failure, or immune deficiency; the method comprising administering a food product with an effective amount of milk mineral to an individual in need thereof. Specifically one of high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, or hypertensive disorders of pregnancy. The milk mineral comprises 60 – 90% mineral, 15 – 30% calcium, 7 – 17% phosphorous, 0 – 15% lactose, 5 – 15% protein, 0 – 5% fat and the food product comprises about 0.1 – 10% of milk mineral.

Art Unit: 1651

Govers teaches administering milk mineral to inhibit colon cancer (abstract) wherein the milk mineral contains 178 mmol/kg calcium, 175 mmol/kg phosphorous, magnesium, potassium, fat and 14% protein (p.95, Materials and Methods).

The reference anticipates the claimed subject matter.

8. Claims 1, 3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitsubori et al. (1990).

Applicant claims a method for treating a disorder selected from high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, hypertensive disorders of pregnancy, type 2 diabetes, depression, asthma, inflammatory bowel disease, attention deficit disorder, migraine headaches, kidney disease, hypercholesterolaemia, congestive heart failure, or immune deficiency; the method comprising administering a food product with an effective amount of milk mineral to an individual in need thereof. Specifically one of high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, or hypertensive disorders of pregnancy. The food product comprises about 0.1 – 10% of milk mineral.

Mitsubori teaches methods for treating hypertension by administering a whey milk mineral diet (abstract) wherein the milk mineral contains potassium, calcium, magnesium and phosphorous (p.94, Materials and Methods).

The reference anticipates the claimed subject matter.

Art Unit: 1651

9. Claims 1, 3 – 4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Howard (US 4237118).

Applicant claims a method for treating a disorder selected from high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, hypertensive disorders of pregnancy, type 2 diabetes, depression, asthma, inflammatory bowel disease, attention deficit disorder, migraine headaches, kidney disease, hypercholesterolaemia, congestive heart failure, or immune deficiency; the method comprising administering a food product with an effective amount of milk mineral to an individual in need thereof. Specifically one of high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, or hypertensive disorders of pregnancy. The food product is selected from acidic juices, acidic beverages, neutral pH beverages, high energy bars, confectionary products, dairy products or bakery products and comprises about 0.1 – 10% of milk mineral.

Howard teaches supplements comprising dried skimmed milk, potassium, magnesium, phosphorous, zinc (abstract), and protein (col.1 line15-35) and methods for treating obesity comprising administering the compositions (col.1 line 5-10). The compositions are made into beverages or milk beverages (dairy products) (col.11 line 1-15, examples).

The reference anticipates the claimed subject matter.

10. Claims 1 and 3 – 7 are rejected under 35 U.S.C. 102(a) and 102 (e) as being anticipated by Girsh (US 2001/0022986 A1).

Art Unit: 1651

Applicant claims a method for treating a disorder selected from high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, hypertensive disorders of pregnancy, type 2 diabetes, depression, asthma, inflammatory bowel disease, attention deficit disorder, migraine headaches, kidney disease, hypercholesterolaemia, congestive heart failure, or immune deficiency; the method comprising administering a food product with an effective amount of milk mineral to an individual in need thereof. Specifically one of high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, or hypertensive disorders of pregnancy. The food product is selected from acidic juices, acidic beverages, neutral pH beverages, high energy bars, confectionary products, dairy products or bakery products, specifically an acidic juice product, more specifically orange juice. The food product comprises about 0.1 – 10% of milk mineral.

Girsh teaches compositions of milk or whey permeate, rich in vitamins and minerals, combined with flavoring agents to form beverages (abstract). The compositions contain potassium (0059), calcium, magnesium, and phosphorous (0062). The flavoring agent may be orange juice (0065). Girsh teaches the compositions in methods of dietary consumption (examples).

Since applicant defines treatment to include treating the disorder as well as prophylactic treatment, the reference anticipates the claimed subject matter.

11. Claims 1 and 3 – 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakagawa et al. (US 5185166).

Art Unit: 1651

Applicant claims a method for treating a disorder selected from high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, hypertensive disorders of pregnancy, type 2 diabetes, depression, asthma, inflammatory bowel disease, attention deficit disorder, migraine headaches, kidney disease, hypercholesterolaemia, congestive heart failure, or immune deficiency; the method comprising administering a food product with an effective amount of milk mineral to an individual in need thereof. Specifically one of high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, or hypertensive disorders of pregnancy. The food product is selected from acidic juices, acidic beverages, neutral pH beverages, high energy bars, confectionary products, dairy products or bakery products, specifically an acidic juice product, more specifically orange juice. The food product comprises about 0.1 – 10% of milk mineral.

Nakagawa teaches a milk mineral composition comprising lactose, potassium, calcium, magnesium, zinc and phosphorous (col.2 line 16-24). The milk mineral is added to drinks such as orange juice in amounts of about 0.01 – 10% (col.2 line 35-40) and is administered for dietary consumption (examples).

Since applicant defines treatment to include treating the disorder as well as prophylactic treatment, the reference anticipates the claimed subject matter.

Art Unit: 1651

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1 – 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Govers, Mitsubori, or Howard in view of Girsh and/or Nakagawa.

Applicant claims a method for treating a disorder selected from high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, hypertensive disorders of pregnancy, type 2 diabetes, depression, asthma, inflammatory bowel disease, attention deficit disorder, migraine headaches, kidney disease, hypercholesterolaemia, congestive heart failure, or immune deficiency; the method comprising administering a food product with an effective amount of milk mineral to an individual in need thereof. Specifically one of high blood pressure, stroke, obesity, kidney stone,

Art Unit: 1651

colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, or hypertensive disorders of pregnancy. The milk mineral comprises 60 – 90% mineral, 15 – 30% calcium, 7 – 17% phosphorous, 0 – 15% lactose, 5 – 15% protein, 0 – 5% fat. The food product is selected from acidic juices, acidic beverages, neutral pH beverages, high energy bars, confectionary products, dairy products or bakery products; is an acidic juice product, specifically orange juice. The food product comprises about 0.1 – 10% of milk mineral.

Govers teaches administering milk mineral to inhibit colon cancer (abstract) wherein the milk mineral contains 178 mmol/kg calcium, 175 mmol/kg phosphorous, magnesium, potassium, fat and 14% protein (p.95, Materials and Methods).

Mitsubori teaches methods for treating hypertension by administering whey milk mineral (abstract) wherein the milk mineral contains potassium, calcium, magnesium and phosphorous (p.94, Materials and Methods).

Howard teaches methods for treating obesity (col.1 line 15-35) comprising administering supplements comprising dried skimmed milk, potassium, magnesium, phosphorous, zinc (abstract), and protein (col.1 line 15-35). The compositions are made into beverages or milk beverages (dairy products) (col.11 line 1-15, examples).

The references do not teach the methods wherein the compositions comprise the specific percents as claimed, or wherein they are incorporated into food products, specifically orange juice at 0.1 – 10%. However, at the time of the claimed invention, milk mineral were routinely incorporated into such food products. In support, Girsh teaches compositions of milk or whey permeate, rich in vitamins and minerals such as potassium, calcium, magnesium, and phosphorous (0059,0062), combined with orange juice (0065) to form beverages (abstract). In

Art Unit: 1651

addition, Nakagawa teaches a milk mineral composition comprising lactose, potassium, calcium, magnesium, zinc and phosphorous (col.2 line 16-24) which is added to drinks such as orange juice in amounts of about 0.01 – 10% (col.2 line 35-40). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to incorporate the compositions of Govers, Mitsubori and/or Howard into food products since it was a well known process as evidenced by Girsh and Nakagawa. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Girsh and/or Nakagawa to incorporate the compositions of Govers, Mitsubori and/or Howard into food products, with a reasonable expectation for successfully treating colon cancer, hypertension and/or diabetes.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1 – 7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19 – 34 of copending

Art Unit: 1651

Application No. 10/371,534. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims include a method of treating obesity with a composition comprising milk mineral in orange juice at 0.01 – 10%.

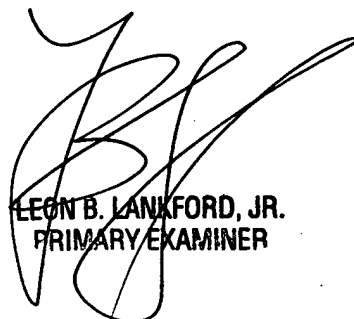
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
September 30, 2003



LEON B. LANKFORD, JR.
PRIMARY EXAMINER